Moving Beyond Crisis to Cure:
Libby Research Center (LRC)
LRC prototype proposal

Program Characteristics/Description

Key objective

To establish a unique clinical research center model in a rural pulmonary clinic (Center for Asbestos-Related Disease (CARD Clinic) in Libby, Mt. where the area population has experienced significant exposure to a transitional amphibole asbestos fiber associated with vermiculite mining, milling, processing, and distribution in operation from 1924 to 1990.

Background history

Results of a community based medical surveillance program involving residents of Libby, Montana demonstrated that 18 % or 994 of 5590 residents (current and former) had pleural abnormalities on chest radiographs, as identified by two certified pulmonologists using the International Labour Office (ILO) classification for pneumoconiosis. The Odds Ratio (OR) for pleural changes in the 45 to 65 year old group was 4.8 (95% CI, 3.8 to 6.0) and for those 65 years or older, the OR was 11.5 (95% CI, 9.1 to 14.6) in comparison to an 18 to 44 year-old baseline reference group. Within the Libby, Montana community, the causative agent of the pleural abnormalities has been environmental exposure to an asbestiform transition fiber with a chemical composition that transitions between tremolite, actinolite, richterite, winchite, and ferro-edenite. This asbestiform mineral contaminates the vermiculite ore source that was mined and milled in the Libby community from 1924 through 1990. From U.S. census 2000 information, there are 10,362 persons living within the Libby zip code and the population is mostly white (95%). Exposure to asbestos-contaminated vermiculite ore occurred through multiple pathways as a result of transport of the ore from the mine and milling sites 3 to 6 miles away to the processing facility in the central area of Libby destined for nonindustrial use in gardens, sandboxes, yards, school running tracks, baseball fields, recreational heat expansion, etc. Through these multiple pathways, young children as well as adults have had frequent and on-going environmental contact with the asbestiform contaminants of the vermiculite ore.

The community based medical surveillance program was undertaken through a partnership with the Agency for Toxic Substances and Disease Registry (ATSDR) in cooperation with DHHS Region VIII office of the United States Environmental Protective Agency (EPA) along with the state and local health departments. From the clinical data, it appears that the asbestiform mineral contaminant has a propensity to cause marked pleural inflammation as manifested by pleural plaques, with or without calcification and diffuse pleural thickening. Interestingly, thus far the prevalence of interstitial changes has been similar to a non-exposed background population at 0.9 % (49 of 5590 residents). The mortality from asbestosis, however, from 1979 through 1998 was 40 to 80 times higher than expected. In addition the lung cancer rate was 20 % to 30 % higher than expected and the mortality from mesothelioma was also highly elevated.

The Libby community is cohesive, very homogeneous, and enthusiastic about participating in both basic science as well as clinical research endeavors regarding the long-term health impact of this environmetal exposure. The nucleus of this community enthusiasm is the locally based Center for Asbestos-Related Disease, Inc., which was established as a bridge for the Libby Community and scientific investigators.

The CARD/LRC has a community-based board of directors and a volunteer scientific advisory committee that helps to identify potential approaches for organizing the Libby cohort for future scientific investigation. Members of the volunteer scientific Committee for Asbestos Related Research (CFARR) include local clinicians as well as investigators from throughout the United States including:

Brooke T. Mossman, Ph.D.
Dr. Mossman is a Research Professor and Director of the Environmental Pathology Training Program at The University of Vermont College of Medicine. Her research interest include environmental toxicology, epithelial cell differentiation, chemical and physical carcinogenesis and cell injury, pulmonary fibrosis, oxygen free radicals, molecular biology of antioxidant enzymes in lung and cell signaling.

James Lockey, M.D.
Dr. Lockey is currently Director of Occupational and Environmental Medicine Division of the University of Cincinnati and has directed or co-directed research on a number of occupational lung diseases. His study of workers at a Marysville, Ohio agricultural company in the mid-1980s demonstrated the adverse pulmonary effects from the use of Libby, Montana asbestos contaminated vermiculite. He has indicated a strong interest in participating in the CARD research project.

Stephen M. Levin, M.D.
Dr. Levin is the Co-Director for the World Trade Center Worker and Volunteer Medical Screening Program. He is Associate Professor at the Mount Sinai School of Medicine. His specialties are Environmental and Occupational Medicine. His clinical interests are occupational medicine; occupational lung disease and heavy metal toxicity.

Alan Whitehouse, M.D.
Dr. Whitehouse is a Board-certified chest physician who has maintained a private practice of pulmonary medicine in Spokane, Washington for the past 33 years. His experience in the evaluation, monitoring, and treatment of individuals exposed to Libby asbestos lends recognition that he offers key expertise in research activities. Dr. Whitehouse has been the CARD clinic's primary consultant and essential support for the clinic's development.

Aubrey Miller, M.D.
Dr. Miller has recently become Senior Medical Officer and Regional Toxicologist for EPA, Region 8, Denver, Colorado. Prior to this, he had been Medical Director Environmental Emergencies and Disasters PHS Region 8 of US Public Health Service. He has extensive experience in public health and epidemiology. He also has been involved intensively in the Libby asbestos project since December 1999.

Andrij Holian, Ph.D.
Dr. Holian returned to Montana in July 2000 to serve as Director of the Center for Environmental Health Sciences at the University of Montana. Immediately prior to his return, he served tenure at the University of Texas Health Science Center since 1984, where he achieved professorship and was Director of Research for Mickey Leland National Urban Air Toxics Research Center. For the past two years, Dr. Holian has been involved in hereditary research into the biologic effects of Libby asbestos.

Brad Black, M.D.
Dr. Black is currently the Medical Director Center for Asbestos Related Diseases in Libby since March 2000. Dr. Black has also served as Lincoln County Health Officer since 1984. Prior to taking the position as Medical Director for the CARD, Dr. Black specialized in pediatrics. Since early 2000 he has attended numerous conferences related to the health affects of asbestos and toxicology. He has worked in close association and consulted with Dr. Alan Whitehouse since late 1999.

Elizabeth Putnam, Ph.D.
After completing undergraduate work in Biochemistry at Rutgers College in New Brunswick, NJ, Elizabeth Putnam earned a Ph.D. in Biomedical Sciences from the University of Texas Graduate School of Biomedical Sciences in Houston. Following postdoctoral fellowships at M.D. Anderson Cancer Center and the University of Texas Medical School, she moved to the University of Montana as a Research Assistant Professor in 2000. Liz was promoted to Assistant Professor in 2002. She is currently studying the role of genetic determinants in the sensitivity of individual populations to environmental insults.

Vikas Kapil, M.D.
Dr. Kapil works for the Agency for Toxic Disease Registry (ATSDR) as a medical officer in the Division of Health Sciences.

Mike Spence, M.D.
Dr. Spence is the State Medical Officer for Montana and is in charge of the Montana Asbestos Screening and Surveillance Activity (MASSA) in Libby.

Ann Cook, Ph.D.
Dr. Cook is the Director of the National Rural Bioethics Project at the University of Montana. She is also an Associate Professor in the Department of Psychology at UM.

Helena Hoas, Ph.D.
Dr. Hoas is the Research Director for the National Rural Bioethics Project at the University of Montana. She is also an Associate Professor in the Department of Psychology at UM

A primary focus of the CFARR is to determine the feasibility of establishing a Libby research center (LRC) within Libby, Montana. In addition, this committee will assist in pursuing funding opportunities and research collaborative partners interested in interacting with the Libby research center. The US EPA and ATSDR have been recommended and selected as the Federal agencies

with the specific interest and mission to ensure the health of residents exposed to environmental contaminants. The CARD believes that this is an outstanding opportunity to build a public/private sector partnership for basic science and clinical research that will have positive impacts not only in Libby, but also throughout the world.

The Mine Safety and Health Administration has listed over 150 minerals that may occur in a fibrous form or that are generally expected to contain fibrous minerals. The most effective means of minimizing disease caused by exposures to these agents is through proper mineralogic identification and appropriate preventive environmental controls. The past, present and yet to be learned future lesson derived from the Libby experience will help manage and prevent the occurrence of pulmonary disease in other communities who have similar type of potential environmental contamination issues to natural occurring mineral fibers.

Proposed Libby Research Center Model

The LRC's primary objective will be to establish, organize and maintain demographic and on-going medical surveillance information within a central database that will subsequently help facilitate basic science and clinical research endeavors involving the Libby cohort. The LRC will encourage investigators at federal and state agencies and academic institutions to submit research proposals through state and federal funding agencies such as National Institute of Environmental Health Sciences (NIEHS). If these proposals are approved and funded, the LRC will help facilitate and coordinate access to the clinical population. The LRC not only will provide a conduit for outside investigators to gain access to a well organized and defined population, but also maintain a tracking database of the cohort. The LRC will serve as an active liaison between outside investigators and the community and help with dissemination of information regarding research protocols, results of future basic science and clinical studies as well as public health preventive health educational endeavors. The LRC will play a critical role in identifying all stakeholders and in developing a risk communication plan and ensuring the implementation of that plan.

Members of the CARD's CFARR are enthusiastic about establishing the LRC within Libby, Montana in coordination with investigators from the University of Montana and the Montana state and local health departments.

The Libby experience is an opportunity to formally organize an environmental exposure cohort in a systematic manner and provide a mechanism for partnership between the local community and qualified investigators from various scientific disciplines throughout the country to assess this population in a coordinated and timely manner. Some of the important questions that will be answered through access to this residential cohort include the following:

- *How does this asbestiform fiber exposure impact children in regard to lung development and restructuring and adult disease manifestation?*
- *What is the rate of progression and degree of disability in view of the propensity for this asbestiform fiber to cause marked pleural inflammation?*
- *How do the pleural and parenchymal compartments differ in their response to this particular fiber?*

- ❖ *Are there genetic differences in regard to pleural inflammation and fibrosis and progression of disease?*
- ❖ *What is the correlation between exposure, pleural and parenchymal abnormalities, and qualitative and quantitative fiber burden within the pleural and lung parenchyma?*

The Libby cohort presents a unique opportunity to answer these and other questions regarding the health impact and pathogenesis of these types of environmental exposures.

CARD Clinic

The CARD Clinic was opened in July of 2000, with the support of the community hospital working with the Lincoln Co. Health Officer. The recognized need and community support for a specialty clinic in Libby partly stemmed from the geographical location and distance (165 miles) to Spokane for pulmonary care where the overwhelming majority traveled. From its inception, the CARD's vision and activities have included developing specialty care and advancing research to better understand the disease mechanisms, ultimately hoping to find promising discoveries benefiting those facing adverse outcomes.

Brad Black, M.D. has been the CARD medical director since its inception, in addition to serving as the Lincoln Co. Health Officer. Alan Whitehouse, M.D. (private practice in Spokane, Wa.) has served as consulting board-certified chest physician. In this role, Dr. Whitehouse has provided oversight of clinic activities, including clinical consultation, set-up and operation of pulmonary function testing, over reading of chest radiography, and other needed specialty support. He has been available on site for 1 day each month. The relationship with Dr. Whitehouse has allowed the CARD Clinic to follow individuals with identified asbestos related abnormality on an annual basis for approximately the past 4 years. The follow-up has included clinical evaluation, full pulmonary functions, chest x-rays, and a significant number of CT scans. The clinic is the storage site of many of the ATSDR screening chest radiographs and a large number of Zonolite (predecessor to W. R. Grace) employee annual chest radiographs.

Currently, there are approximately 1,000 patients followed regularly at the clinic, although the patient-base will grow to 1400-1500 by December of 2004 as Dr. Alan Whitehouse transitions his practice from Spokane to the CARD. Dr. Whitehouse will become a full-time CARD employee by January 2005.

CARD outreach services include psychosocial support as well as community education and outreach. This aspect of the CARD is critically important to individual patients and the community as a whole as both must deal with the mental and physical health issues and the social and economic ramifications that have resulted from environmental contamination of the Libby community.

CARD Board and Staff Personnel

CARD, Inc. is a nonprofit 501(c) 3 organization whose board is composed of volunteer community members dedicated to the vision of "Caring Pathways to Treatment". This nine-

member board is in the process of creating the enhanced availability of pulmonary specialty care in Libby through expansion of its staff with the employment of Dr. Alan Whitehouse. The board is also dedicated to the development of a research center and understands the importance of necessary restructuring to facilitate a research component harmonious with present CARD Clinic care that is acceptable for research funding consideration. Although the CARD has been an independent nonprofit for only 14 months, the board due to current space constraints within the hospital complex unanimously approved the purchase of an existing clinic in Libby (with twice the square footage at half the current rental rate). The board and the staff then donated the necessary five figure down payment to purchase the facility. Although a forty-five year old facility, with renovation it will serve the CARD and LRC needs for the next 18 to 24 months until an expanded facility can be built which will accommodate the growth anticipated by the LRC.

Dr. Brad Black – CARD Medical Director
Dr. Black was board-certified in Pediatrics in 1978 after having begun private practice in Libby in 1977. As a resident of Libby for the past 27 years, he is a member of the Libby asbestos-exposed cohort. He has spent the past 4 years evaluating the pulmonary health of Libby residents in close consultation with Alan Whitehouse, M.D., Spokane chest physician. Dr. Black has attended multiple conferences with a diverse group of individuals knowledgeable in the pneumoconiosis and pulmonary medicine. He had worked closely with the EPA and ATSDR to develop the Libby asbestos screening protocol, and serves on the Tremolite Asbestos Registry (TAR). He has had the opportunity on two separate occasions to speak at the Big Sky Pulmonary Conference hosted by the American Lung Association, Northern Region.

Dr. Alan Whitehouse – Staff pulmonologist
Dr. Whitehouse completed two years of internal medicine residency at Duke University Medical Center in 1965, and finished his residency and pulmonary fellowship at the University of Colorado Medical Center in 1969. Since receiving his boards in internal medicine and pulmonary disease, Dr. Whitehouse has been in private practice as a chest physician in Spokane since 1969. He has followed many Libby patients with pulmonary disease for at least 30 years, and identified significant lung disease due to environmental asbestos exposure in Libby. This resulted in an ATSDR study of his environmental cases as well as the ATSDR community-screening program. His Spokane practice includes at least 400 patients diagnosed with asbestos related disease resulting from exposure to the asbestiform transition fiber contaminating the Libby community. He has followed and collected extensive pulmonary function and radiographic studies over 10-15 years. He developed a recognition of the unique property of the Libby asbestiform transition fiber and its propensity to cause extensive pleural disease that can lead to significant pulmonary impairment. Dr. Whitehouse has recently analyzed disease progression in his longer established Libby exposed patients and anticipates publication of his observations within a peer reviewed journal in the near future.

Pat Cohan, RN, CCN – Nurse Coordinator
Pat Cohan, RN has acted in the capacity of clinic nurse in addition to performing administrative duties as well as supervising other staff. She assists the management team in all aspects of clinic operations. Additionally, she has been instrumental in directing staff and providing patient care and education. She has participated in collaboration with the University of Montana in obtaining

serum for research endeavors. Pat Cohan reports to the medical director, carries out administrative functions on his behalf, and has been a key contact person for the CARD Clinic.

Tanis Hernandez, MSW – CARD CORA Program Coordinator
Helen Clarke – CARD/UofM E:ABCs Project Coordinator
CARD Outreach for Recovery Assistance (CORA) provides outreach, education, and assistance in addressing the physical and mental health impacts, in addition to the social, financial, and lifestyle impacts that has been the result of the environmental contamination of the Libby community. CORA provides outreach services on multiple level, from community-wide public education to individual outreach. CORA has also created a training manual to assist other communities in establishing outreach programs that address the multi-faceted long-term impacts that can occur with this type of environmental public health disaster.
Ethics: A Bridge for Communities and Scientists (E:ABCs) develops innovative, accessible educational curriculum based on public surveys that facilitates understanding of the multifaceted elements associated with the type of public health issues being experienced by the Libby community. This includes translating scientific findings into layman terms and disseminating this information to the community. E:ABCs will assess the impact of all educational interventions to ensure methodologies are responsive to evolving needs and can be adapted to other communities facing similar disasters.

Other CARD personnel include:
Bob and Vicki Munson – Development Team
Debbie Crawford – Office Coordinator
Julie Munro – Medical Assistant
Cheryl Fox – Research Assistant

All CARD personnel, at both the board and staff level, enthusiastically support the establishment of the Libby Research Center and are enthusiastic about working with the CFARR, ATSDR and the EPA in order to build a sustainable research model designed to make a difference that counts!